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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/441,875	11/17/99	CHARLTON	D CWP-012CN3

HM12/0706

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EXAMINER

DO, P

ART UNIT	PAPER NUMBER
1641	3

DATE MAILED: 07/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/441,875	Applicant(s) Charlton et al.
	Examiner Pensee T. D	Group Art Unit 1641



Responsive to communication(s) filed on Nov 17, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 14-26 is/are pending in the application.
 Of the above, claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 14-26 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Amendment Entry

1. The preliminary amendment filed on November 17, 1999 has been acknowledged and entered.

Drawings

2. The drawings are objected to because of reasons indicated in Form PTO-948 (Notice of Draftsperson's Patent Drawing Review). Correction is required.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 14, line 8, "permeable material" lacks antecedent basis.

Claim 14 is indefinite for reciting "capable of" in line 8 because it is not clear as to how the permeable material is modified to be "capable of" transporting an aqueous solution.

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 14-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown, III et al. (EP 217 403 A2).

Brown, III et al. describes a test device (10) comprising a casing (14) defining a sample inlet and viewing window (fluid chamber 7) and having disposed therein a test strip comprising a sorbent material 20 (sorbent material for reservoir volume) and a porous fiber matrix 12 (equates to the claimed permeable material) and a test site (34) comprising, e.g. an immobilized first protein to a ligand, and a control site (32) comprising, e.g. immobilized second protein (i.e. an immobilized binder which binds to the conjugate, which conjugate binds to the ligand), and preferably a filter means (22), which device is useful for competitive, sandwich and indirect immunoassays. Chorionic gonadotropin is an explicitly illustrated ligand (example 3). Particles coated with first protein are immobilized within the porous fiber matrix 12 (permeable material) (See col. 4, line 49-col. 5, line 2). The first protein and second protein consists of a variety of monoclonal antibodies or polyclonal antibodies. (See col. 5, lines 54-56). The sorbent means 20 disposed in the casing 14 is for absorbing excess fluids during use of the assay device. The absorbent means 20 comprise one or more layers of material and is in physical contact with the barrier material 18, when used, or with the reaction matrix 12. (See col. 10, lines 29-46).

Double Patenting

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7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 14-26 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, 9, 11 of prior U.S. Patent No. 5,989,921. This is a double patenting rejection.

Patent 5,989,921 teaches a test device for determining the presence of a ligand in a liquid sample, the device comprising:

a casing defining an inlet and at least one window for a test strip disposed within said casing comprising a sorbent material which defines a flow path for transporting the liquid sample there along from said inlet to a test site and a control site, and,

disposed upstream of said test site and said control site, a conjugate comprising a specific binder for the ligand and a colored particulate material,

said test site comprising an immobilized first binding protein which binds specifically to the ligand, if the ligand is present in the liquid sample and said control site comprising an immobilized binder which binds said conjugate; wherein said inlet, said test site and said control site are in lateral flow fluid communication along said flow path, such that after a liquid sample suspected to contain the ligand is applied to said inlet, said conjugate moves along said flow path and binds to

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said immobilized binder of said control site to produce a color visible to the unaided eye through said at least one window indicative of a valid test result, and if the ligand is present in the liquid sample, a specific binding reaction product comprising the ligand and said conjugate binds to said immobilized first binding protein of said test site to produce a color visible to the unaided eye through said at least one window indicative of the presence of the ligand in the sample. The test device further comprises a filter in said flow path upstream of said test site and control site and said filter is defined by a portion of said sorbent material. The control site is located downstream of said test site. The control site is a positive control site. The first protein binds human chorionic gonadotropin. The first protein binds human progesterone. At least one of first and second binding proteins is a monoclonal antibody.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri. from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641

Pensee T. Do
Patent Examiner
June 30, 2000